K122569

SEP 12 2012

3M ESPE
Dental Products

3M Center
St. Paul, MN 55144-1000
651 733 1110

3M ESPE

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Submitter..... 3M Company
3M ESPE Dental Products
3M Center, Bldg. 275-2W-08
St. Paul, MN 55144-1000 USA

Contact person..... Ginger Cantor, RAC
Regulatory Affairs Specialist
Phone: (651) 733-1317
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gcantor@mmm.com

Date Summary was Prepared.....August 21, 2012

Trade Name.....Lava™ Ultimate CAD/CAM Restorative for CEREC®
Lava™ Ultimate CAD/CAM Restorative for E4D®
Lava™ Ultimate Implant Crown Restorative
Lava™ Ultimate CAD/CAM Restorative for Straumann®

Common Name(s).....Dental material, filling/restorative, polymer based

Recommended Classification.....Tooth shade resin material
(21 CFR 872.3690, Product Code: EBF)

Predicate Devices:
3M ESPE's Lava Ultimate CAD/CAM Restorative (K110131)
Ivoclar Vivadent AG's IPS e.max Press (K982616)

Description of Device:
The product is a strong, wear-resistant and highly esthetic mill block that provides a fast and easy-to-use alternative to porcelain blocks for milling CAD/CAM indirect restorations. The material is specially processed to enhance its properties for use in CAD/CAM milling procedures.

Indications for Use:
Lava Ultimate restorative is indicated for inlays, onlays, veneers, full crown restorations, including implant supported crowns, permanent three unit bridges in the anterior region and permanent three unit bridges in the premolar region up to the second premolar as the terminal abutment. The bridge consists of two full crown abutments supporting a pontic between them; the two abutments may be either two teeth or two implants.

Lava Ultimate restorative is not indicated for uses other than those listed.

Contraindications
Lava Ultimate is contraindicated for bridges in patients with parafunctional habits such as bruxism (hyperfunction) or clenching.

Substantial Equivalence:

Information provided in this 510(k) submission shows that the product is substantially equivalent to the 3M ESPE's predicate device Lava Ultimate (K110131) and to Ivoclar Vivadent AG's IPS e.max Press (K982616).

This 510(k) submission includes data from in-vitro testing of prepared anterior bridges to evaluate the performance of Lava™ Ultimate CAD/CAM Restorative compared to Ivoclar Vivadent AG's IPS e.max Press (K982616).

No additional biocompatibility testing was required to support the submission - the formulation of Lava Ultimate has not changed since clearance of its original 510(k) (K110131).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 12 2012

3M Company
C/O Mr. Mark Job
Regulatory Technology Services, Limited Liability Company
1394 25TH Street, North West
Buffalo, Minnesota 55313

Re: K122569
Trade/Device Name: Lava™ Ultimate Cad/Cam Restorative for Cerec®
Lava™ Ultimate Cad/Cam Restorative for E4D®
Lava™ Ultimate Implant Crown Restorative
Lave™ Ultimate Cad/Cam Restorative for Straumann®
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: September 7, 2012
Received: September 10, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898.

In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122569

Indications for Use

510(k) Number (if known):

Device Name: Lava™ Ultimate CAD/CAM Restorative

Indications for Use:

Lava Ultimate restorative is indicated for inlays, onlays, veneers, full crown restorations, including implant supported crowns, permanent three unit bridges in the anterior region and permanent three unit bridges in the premolar region up to the second premolar as the terminal abutment. The bridge consists of two full crown abutments supporting a pontic between them; the two abutments may be either two teeth or two implants.

Lava Ultimate restorative is not indicated for uses other than those listed.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122569